REMARKS

I. The Election/Restriction Requirement

The Examiner claims that the present application contains claims directed to more than one species of the generic invention. According to the Examiner, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive step concept under PCT Rule 13.1.

The Examiner asserts that the species fall within the groups as indicated:

Direct thrombin inhibitors: (a) Argatroban, (b) bivalirudin, (c) efegatran, (d) inogatran, (e) desirudin, and (f) lepirudin, as in claims 4-6 and 10-13.

Anticoagulants: (g) lepirudin, (h) enoxaparin, (i) dalteparin, (j) tinzaparin, (k) bivalirudin, and (l) fondaparinux, as in claim 2.

Applicants are required, in reply to this action, to elect a single species from each of the above groups to which the claims shall be restricted if no generic claim is finally held to be allowable. Applicants respectfully traverse the Examiner's election/restriction requirement, but, solely for the sake of submitting a complete response, Applicants select (a) Argatroban from the direct thrombin inhibitor group and (l) fondaparinux from the anticoagulant (non direct thrombin inhibitor) group. All claims are covered by this election, either generically (see claims 1 and 7-9, where the word "anticoagulant" is used and claim 3, where "anticoagulant" and "direct thrombin inhibitor" is used) or specifically (see claims 4-6 and 10-13 where "Argatroban" is used, and claim 2, where fondaparinux is used) .

The Examiner seems to have artificially divided anticoagulants into two groups: direct thrombin inhibitors and non direct thrombin inhibitors. The present invention involves the

administration of an anticoagulant to a patient undergoing treatment for HIT or at risk for HIT. Thus there should be no further division in this case.

The instant invention was filed under the provisions of 35 U.S.C. §371 as a national stage filing of a PCT patent application. Thus, the standard applicable to the instant application is "unity of invention" under the PCT. *See* MPEP § 1893.03(d). In the instant case no lack of unity of invention was found by the International Searching Authority or the International Preliminary Examining Authority, and all claims were searched and examined as one invention.

PCT Rule 13.1 includes within the definition of Unity of Invention "a group of inventions so linked as to form a general inventive concept." Independent, as defined in MPEP 802.01, "means that there is no disclosed relationships between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect." In the present case, the invention involves the continuous administration of an anticoagulant to restore platelet counts in a patient undergoing treatment. This represents one general inventive concept and the anticoagulants in question are connected in design, operation and effect in that they prevent coagulation during the course of treatment for HIT. Thus, the claims can not be further subdivided or restricted, and the inventions of the pending claims must be included in a single application.

Further, the Examiner's analysis is out of ambit with any reasonable interpretation of PCT rule 13.2. All the claims of the present invention represent the "special technical features" made over the prior art. Again, this involved the administration of an anticoagulant during the course of treatment until platelet counts are restored.

The purpose of a restriction requirement is to assure that one invention is claimed. If one invention is claimed, the invention must not be restricted.

It is also noted that a Restriction Requirement is at the discretion of the Examiner and the Examiner is request to exercise said discretion to withdraw this Restriction Requirement.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number indicated below.

Respectfully submitted,

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